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DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

Food & Drug Administration
850 Third Avenue
Brooklyn, NY 11232

July 7, 1999

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED
Mr. Peter F. Brunelli, President
Universal Medical Systems, Inc.,
299 Adams Street
Bedford Hills, New York 10507

Ref: NYK-1999-50

Dear Mr. Brunelli:

During an inspection of your firm located in Bedford Hills, New York on February 23rd, 24th and March 8th, 1999 our investigator determined that your firm imports, distributes, relabels and refurbishes ultrasound systems for human use such as the Aloka SSD 500 and SSD 900 series, the SONOACE 600, the SDL-32, the Genesis 3000Ap and the SDU450 models. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act). The aforementioned devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packaging, storage or installations are not in conformance with the Current Good Manufacturing Practice (GMP) as specified in Title 21, Code of Federal Regulations, (CFR), Part 820, Quality System Regulations, as follows:

1. Failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints. [21 CFR 820.198].

2. Failure to ensure that all inspection, measuring and test equipment, including mechanical, automated, or electronic inspection and test equipment, is suitable for its intended purposes and is capable of producing valid results in that you failed to calibrate test equipment and maintain procedures and records to ensure that the test equipment is routinely calibrated, inspected, checked and maintained as required by 21 CFR 820.72(a). Specifically the following testing instruments were not calibrated:
   a) Wavetek digital voltmeters, serial numbers: 96107794 and 50412835;
   b) Beckman digital voltmeters, serial numbers: 10327414 and 930429093; Tektronix Oscilloscopes, serial numbers: B020407 & B020690.

3. Failure to establish and maintain procedures for inspecting ultrasounds systems as required 21 CFR 820.72(a) and 820.75(b).

4. Failure to have established and maintain procedures for acceptance of incoming products to ensure that they are inspected, tested or otherwise verified as conforming to specified requirements as required by 21 CFR 820.80. Specifically, maintenance of adequate test results for ultrasounds purchase as "trade-ins" that are repaired or re-programmed for further distribution to a customer who does not represent the original owner of the device is not being accomplished. For example, work orders display test results that do not indicate the acceptance criteria "Pass" or "Fail" status but merely indicates that the final test is "OK".

5. Failure to have established procedures for identifying training needs and to ensure that all personnel are trained to adequately perform their assigned responsibilities as required by 21 CFR 820.25. Specifically:
   a) Failure to have training procedures that identify training needs and to ensure that personnel (in particular those working in the service department) are trained to adequately perform their assigned responsibilities without adversely affecting the original design of the device.
   b) Failure to document training received by individuals who perform repairs on ultrasounds.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA-483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no pending applications for premarket approval (PMA's) or export approval requests will be approved and no Premarket notifications [Section 510(k)s] will be found to be substantially equivalent for products manufactured at the facility in which the above GMP violations were found until the violations have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction and/or civil penalties.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations. Include an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be directed to the Food and Drug Administration, 850 Third Avenue, Brooklyn, New York 11232, attention: Anita Fenty, Compliance Officer. If you have any questions, Ms. Fenty's telephone number is (718) 340-7000 ext. 5053.

Sincerely,

Brenda J. Holman
District Director

Enclosure: FDA form 483